Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program
Supporting Statement Part A
OMB#: 0938-1016; CMS-10169

Background

Since 1989, Medicare has been paying for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) (other than customized items) using fee schedule amounts that are calculated for each item or category of DMEPOS identified by a Healthcare Common Procedure Coding System (HCPCS) code. Payments are based on the average DMEPOS supplier charges on Medicare claims from 1986 and 1987 and are updated annually on a factor legislated by Congress. For many years, the Government Accountability Office (GAO) and the Office of Inspector General (OIG) of the United States (U.S.) Department of Health and Human Services (DHHS) have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DMEPOS. Due to reports of Medicare overpayment of DMEPOS, Congress required that the Centers for Medicare & Medicaid Services (CMS) conduct a competitive bidding demonstration project for these items. Accordingly, CMS implemented a demonstration project for this program from 1999-2002 which produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. Shortly after the successful competitive bidding demonstrations, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act" or "MMA") and mandated a phased-in approach to implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). This statute specifically required the Secretary to establish and implement programs under which competitive bidding areas (CBAs) are established throughout the U.S. for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the Medicare DMEPOS Competitive Bidding Program (the Program).

CMS conducted its first round of bidding, Round 1, for the Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor (CBIC). CMS published a Request for Bids (RFB), instructions, and accompanying forms for DMEPOS suppliers to submit their bids to participate in the Program. During this first round of bidding, DMEPOS suppliers from across the U.S. submitted bids identifying the MSA(s) to service and the competitively bid item(s) they wished to furnish to Medicare beneficiaries. CMS evaluated these bids and contracted with those bidders that met all program requirements. Round 1 was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed the Program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the Program which included, but was not limited to: a delay of Round 1 (competition to begin in 2009) and Round 2 of the Program (competition to begin in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy (NPWT) from Round 1 and Group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to bidders regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of the MIPPA specified that the competition for national mail-order (NMO) items and services may be phased in after 2010. This section of MIPPA also specified that competitions to phase-in additional areas could occur after 2011. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011. The Affordable Care Act (ACA), enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a NMO competition for diabetes testing supplies (DTS) at the same time as Round 2. The Round 2 and NMO DTS contracts and prices were implemented on July 1, 2013.

The MMA requires the Secretary to recompete contracts not less often than once every three years. The Round 1 Rebid contract period for all product categories except NMO DTS expired on December 31, 2013. (Round 1 Rebid contracts for NMO DTS ended on December 31, 2012.) The competition for the Round 1 Recompete began in August of 2012 and contracts and prices became effective on January 1, 2014. The Round 1 Recompete contract period expired on December 31, 2016. Round 1 2017 contracts became effective on January 1, 2017, and expire on December 31, 2018. Round 2 and NMO DTS contracts and prices expired on June 30, 2016. Round 2 Recompete and the NMO DTS Recompete contracts became effective on July 1, 2016, and expire on December 31, 2018. CMS will be implementing a consolidated round of competition to include all Round 1, Round 2, and the NMO CBAs in the next round.

Additionally, Section 1847(a)(1)(G) of the Social Security Act (the Act), added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA), requires a bid surety bond for bidding entities beginning not earlier than January 1, 2017, and not later than January 1, 2019. Based on the passage of MACRA, we proposed additions to §414.412, "Submission of bids under a competitive bidding program," to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA. CMS published the proposed rule CMS-1651-P on June 30, 2016. The comment period on this rule closed on August 23, 2016. CMS published the final rule CMS-1651-F on November 4, 2016.

CMS previously discontinued this Information Collection Request (ICR) while the new CMS administration was reviewing the Program. As a result of the administration's review, CMS published the finalized changes to the Program in CMS-1691-F on November 14, 2018 ((83 FR 59622)[1]. We are now seeking approval to reinstate the ICR and to update our burden estimates to Forms A and B in preparation for the next round. CMS will publish a slightly modified version of Form A so that bidders will be better able to identify and understand the new requirement related to bid surety bonds. We have made changes to Form B to remove the expansion plan section and to include the bidding methodology proposed in CMS-1691-P.

The Program, combined with other fraud, waste, and abuse initiatives, has saved Medicare over $2 billion per year.

A. Justification

1. Need and Legal Basis

Section 302 of the MMA amended section 1847 of the Act to require the implementation of the Program. The Act provided the Program requirements for the submission of bids in establishing payment amounts and the awarding of contracts; provided the requirements for mergers and acquisitions; and a requirement for the Secretary to re-compete contracts not less often than once every three years. These regulations were published on April 10, 2007 (72 FR 17992).

In the January 16, 2009, Federal Register (74 FR 2873), we incorporated a number of provisions in the MIPPA related to the Round 2 and NMO competitions. We also indicated that we would streamline financial documents collected as part of the RFB to include one year of documents instead of the three years collected in the 2007 Round 1 competition.

[1] CMS- 1691-F Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS

Section 6410 of the ACA amended section 1847 of the Act to add 21 MSAs to the 70 MSAs MIPPA designated for the Round 2 competition, for a total of 91 MSAs.

In the November 29, 2010, **Federal Register** (75 FR 73611) we incorporated the statutory requirement to conduct the Round 2 competition in 91 MSAs into our regulations and established the requirements for conducting a NMO competition for DTS.

Section 1847(a)(1)(G) of the Act, added by section 522(a) of the MACRA, now requires a bid surety bond for bidding entities beginning not earlier than January 1, 2017, and not later than January 1, 2019. The addition to the Act states that a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of $50,000 to $100,000 and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s).

Based on the passage of MACRA, we put forth proposed additions to §414.412, "Submission of bids under a competitive bidding program," to add a new paragraph (h) that would allow CMS to implement section 1847(a)(1)(G) of the Act, as amended by section 522(a) of MACRA, to state that an entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has obtained a bid surety bond for the CBA.

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2. Information Users

Bidding Forms A and B:
DMEPOS suppliers submit bids in order to compete to become a contract supplier to furnish competitively bid items to Medicare beneficiaries who live in or visit a CBA. CMS publishes a RFB and instructions to specify Program requirements and to instruct bidders through the bid submission process. Bids are submitted electronically via the DMEPOS Bidding System (DBidS), the Program's online bidding system. The bids submitted by the close of the bid window are evaluated to determine which bidders will become contract suppliers. All information submitted by the bidders is considered and evaluated. Form A collects key business information to identify a bidder, the areas and products where the bidder chooses to bid, and pertinent information to support that the bidder meets all eligibility requirements. A thorough analysis is performed of all information submitted to determine that the bidder has met all requirements, including licensure, financial, and quality standards. Form B contains key bid information including the bid amount for each item, historical experience providing each item, and specific manufacturer and model information for each item. The manufacturer and model information is utilized to populate the Medicare Supplier Directory during the contract period for bidders that are awarded a contract. CMS utilizes the combined information from Forms A and B to select winning bidders and establish single payment amounts for competitively bid items and services.

3. Use of Information Technology

Bidding Forms A and B:
All bidders must submit their information, and signature(s) electronically into Forms A and B using DBidS. This system allows bidders to efficiently and consistently provide the necessary information. Bidders are allowed to make changes to their bids at any time prior to the close of the bid window, at which time bidders are required to complete, approve, and certify their bids. The CBIC will use the appropriate technology to safely obtain and secure the bidding information that is transmitted. Assistance and technical support is available to bidders throughout the competitive bidding

process. Bidders will be required to submit supporting documentation such as required financial documents, proof of a bid surety bond(s), and any network agreements to the CBIC.

4. Duplication of Efforts

Bidding Forms A and B:
This information collection does not duplicate any other effort, and the information cannot be obtained from any other source.

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5. Small Businesses

These information collections will impact small businesses. However, CMS has attempted to reduce the burden on small suppliers by requiring them to submit only those forms that are essential to implement the Program according to regulations. CMS has made an effort to minimize the burden associated with the process by publishing guidance with fact sheets, frequently asked questions, and providing online forms with checklists of other required documents.

In developing bidding and contract award procedures, section 1847 (b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the Program. Section 1847(b)(2)(A)(ii)) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards. We note that CMS has also implemented numerous regulatory provisions to reduce burden on small suppliers. These provisions are described in the April 10, 2007, and January 16, 2009, regulations and will remain in effect for future rounds of competition.

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6. Less Frequent Collection

Bidding Forms A and B:
Section 1847 of the Act requires suppliers interested in participating in the Program to submit a bid for every new round of competition in order to be considered for the award of a contract. The Secretary is required to recompete contracts not less often than once every three years. During the bidding process, each bidder will be required to submit one Form A. Bidders will be required to submit one Form B for each product category and CBA for which a bid is submitted. The statute provides no options for less frequent collection.

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7. Special Circumstances
There are no special circumstances related to the collection of information for the Program.

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8. Federal Register/Outside Consultation

Federal Register

The 60-day Federal Register notice published on July 19, 2018 (83 FR 34304) as part of the rulemaking document CMS-1691-P. No public comments were received on the information collection requirements.

Outside Consultation

There was no outside consultation related to the collection of information for the Program.

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9. Payments/Gifts to Respondents

We will not be providing gifts or any payments (other than remuneration under the contract) to contract suppliers.

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10. Privacy

CMS will maintain the confidentiality of proprietary and financial information to the extent provided by law and will follow the procedure stated in 45 CFR 5.65. CMS will not share information about any bidder with other entities. However, an independent evaluator may be granted access to a bidder's information as permitted by law. Any reports that are created to evaluate the Program will be reported in an anonymous or aggregate format. Bidder information may be reviewed as required by law by the GAO and the DHHS OIG, and by the Department of Justice (DOJ). CMS will request that any reports created to evaluate the Program by the GAO and DHHS/OIG will report information in an anonymous or aggregate format.

All U.S. Federal Government contractor staff with access to bidder's information will be required to sign a statement agreeing to maintain the confidentiality of each bidder's information.

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11. Sensitive Questions

There are no questions of a sensitive nature related to the collection of information for the Program.

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12. Burden Estimates (Hours and Wages)

Bidding Form A
Form A is used to identify the bidder. This form includes information for all locations that will be included with the bid(s). In preparation for the next round, this form will also provide new instructions in accordance with §414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid.

We estimate the time to obtain a bid surety bond from a surety company (including contacting the company, filling

out forms, submitting forms, filing paperwork, etc.) to be 11 minutes. Additionally, we estimate that the time to assemble and complete the new bid surety bond section of Form A to be 5 minutes. The time to submit the bid surety bond documentation is estimated to take an additional 5 minutes. Therefore, the total time to compete Form A has changed from 8 hours to 8 hours and 21 minutes. We have estimated the number of respondents (bidders) for the next round based on our experience from prior rounds of competition. Each bidder will be required to complete one Form A for each round in which it bids. We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of $49.70, plus fringe benefits and overhead of $49.70, for a total of $99.40[2]. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate a bid. We estimate, based on information from previous rounds of competition, the burden for each bidder to complete Form A is 8 hours and 21 minutes, and $829.99. This estimate is based on the time it takes a bidder to develop their business strategy on which CBAs and product categories to bid; obtain their bid surety bond(s); gather the required documents; and enter and review their information. We do not know the exact number of bidders who will bid in the next round; however, for purposes of this paperwork burden estimate, we will assume that the number of bidders will be roughly the same as in previous rounds of competition. We estimate there will be approximately 1,500 bidders in the next round and each bidder will complete Form A once for a total of 12,525 hours and a total cost of $1,244,985. Our total and annualized burden estimates for Form A are as follows:

Form A			
Round	**Total Number of Bidders**	**Total Hours**	**Total Cost**
Next round	1,500	12,525	$1,244,985
Annualized Total	500	4,175	$414,995

Bidding Form B

Bidders will use Form B to submit bids for items included in the Program. This form will be completed once for each CBA and product category combination with an estimated completion time of 3 hours. Total completion time assumes the time it takes a bidder to develop their bid amount and enter the applicable information into Form B. For the next round, we do not know how many bids will be submitted; however, for purposes of this estimate, we would assume the average bidder would bid in 5 CBAs in 7 product categories for an average total of 35 Form Bs. We expect the number of hours to complete Form B to decrease based on the removal of the expansion plan section, as well as the proposed change in bidding methodology to move to lead item pricing as published in CMS-1691-P. Specifically, the expansion plan section is being removed from Form B to reduce the burden for bidders by streamlining the bidding process. The proposed change in the bidding methodology to move to lead item pricing will require bidders to only submit a single bid for an entire product category, instead of multiple bids (which can be over 100 for some product categories). We anticipate that this form will be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of $49.70, plus fringe benefits and overhead of $49.70, for a total of $99.40[3]. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate the bid. As a result, we estimate it will require the average bidder 105 hours to complete all 35 Form Bs with a cost of $10,437. Assuming 1,500 bidders participate in the next round of the Program, and each bidder completes 35 Form Bs, there will be estimated 52,500 Form Bs submitted taking an estimated 157,500 hours for a total estimated cost of $15,655,500.

[2] This wage is based on the May 2017 Occupational Employment Statistics from the Bureau of Labor Statistics plus fringe benefits and overhead, https://www.bls.gov/oes/current/oes113011.htm

[3] This wage is based on the May 2017 Occupational Employment Statistics from the Bureau of Labor Statistics plus fringe benefits and overhead, https://www.bls.gov/oes/current/oes113011.htm

Form B				
Round	**Total Estimated Number of Bidders**	**Total Estimated Number of Form Bs Based on 35 Per Bidder**	**Total Hours**	**Total Cost Based on the Total Hours multiplied by the Mean Hourly Wage**
Next round	1,500	52,500	157,500	$15,655,500
Annualized Total	500	17,500	52,500	$5,218,500

Annual Burden Summary:
The following table includes the burden estimates associated with this PRA application.

Burden Summary			
Form	**Annual Responses**	**Annual Hours**	**Annual Cost**
Form A	500	4,175	$414,995
Form B	17,500	52,500	$5,218,500
Total	18,000	56,675	$5,633,495

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13. Capital Costs

The information required is information that is readily available to DMEPOS suppliers, and they should have the equipment necessary to collect and furnish the information. The equipment needed to process these forms is the same equipment that would be needed to provide routine business functions. As a result, there should be no extra capital cost to respondents for recordkeeping resulting from the collection of this information.

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14. Cost to Federal

Government

Form A and B Costs
The government incurs approximate annual costs of $1.5 million for contractor work to operate and maintain the DBidS system. These costs are more than offset by the savings resulting from Program implementation. The Program, combined with other fraud, waste, and abuse initiatives, has saved Medicare over $2 billion per year.

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15. Changes to Burden

The variables impacting burden are unique to each round of competition. Variables contributing to burden differences between rounds of competition include the number of bidders, the number of bids, number of product categories, and the number of CBAs. We have described the anticipated variability based on historical data and/or estimates from past experience including the implementation of the next round and the new requirement for a bid surety bond for bidders submitting a bid(s).

In preparation for the next round of bidding, we have made changes to Form A to better clarify the new bidding requirement related to bid surety bonds. The changes to Form A provide new instructions in accordance with §414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid. Bidders must submit a copy of each bid surety bond to the CBIC prior to the close of the bid window. We expect the number of hours to complete Form B to decrease based on the removal of the expansion plan section, as well as the proposed change in the bidding methodology to move to lead item pricing as published in CMS-1691-P. Specifically, the expansion plan section is being removed from Bidding Form B to reduce the burden for bidders by streamlining the bidding process. The proposed change in bidding methodology to move to lead item pricing will require bidders to only submit a single bid for an entire product category. In addition, we have removed From C, Form D, Change of Ownership, and the Subcontracting forms from this ICR and will be including them in a subsequent ICR package as we are reviewing them for possible updates.

The total burden for this package has decreased since the last PRA application was approved by OMB as a result of the planned consolidation of the next round of competition to include the Round 1, Round 2, and NMO CBAs, more accurate estimates based on our experience from prior rounds of competition, more bidders who are experienced with the Program, information technology efficiencies in the bidding process (DBidS), the bidding methodology proposed in CMS-1691-P, and the exclusion of other forms for the Program that will be included in a subsequent PRA application . We are revising this package to adjust the burden accordingly. In the Background section, we have described the method to report the total burden associated with use of these forms.

The previous ICR reflected additional burden for Forms A and B because information had to be collected for Round 1 2017, Round 2 Recompete, and the NMO Recompete. This information has already been collected and therefore is not applicable for this ICR. Information collection for these forms will be applicable when bidding begins for the next round. In this ICR, the annual burden for Form A for the next round is 500 responses and 4,175 hours. The annual burden for Form B for the next round is 5,218,500 responses and 52,500 hours.

	Total Request	**Previously Approved**	**Change**	**Reason for Changes**
Annual Number of Responses	18,000	37,496	-19,496	Round consolidation (multiple rounds to single round), more accurate estimates based on our experience from prior rounds of competition, more bidders who are experienced with the Program, information technology efficiencies in the bidding process (DBidS), the bidding methodology proposed in CMS-1691-P, and the exclusion of other forms for the Program that will be included in a subsequent PRA
Annual Time Burden (Hr)	56,675	234,194	-177,519	

				application.

16. Publication/Tabulation Dates

There are no plans to publish any of the information collection detailed in this package.

17. Expiration Date

CMS will display the expiration date at the bottom of Form A and Form B upon approval from OMB.

18. Certification Statement

There are no exceptions to the certification statements.

B. Collection of Information Employing Statistical Methods

This collection of information does not employ statistical methods.